UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE GENERIC DIGOXIN AND DOXYCYCLINE ANTITRUST LITIGATION	MDL NO. 2724 16-MD-2724
	HON. CYNTHIA M. RUFE
THIS DOCUMENT RELATES TO: DIRECT PURCHASER ACTIONS	COMPLAINT – CLASS ACTION

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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Plaintiffs KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., Rochester Drug Co-Operative, Inc., Cesar Castillo, Inc. and Ahold USA, Inc. (collectively "plaintiffs"), bring this Consolidated Amended Class Action Complaint on behalf of themselves and on behalf of a class of direct purchasers (hereinafter referred to as "class members") who purchased generic digoxin or doxycycline[1] from defendants Lannett Company, Inc. ("Lannett"), Impax Laboratories, Inc. ("Impax"), West-Ward Pharmaceuticals Corporation ("West-Ward"), Actavis Holdco U.S., Inc. ("Actavis"), Par Pharmaceutical, Inc. ("Par"), Sun Pharmaceuticals, Inc. ("Sun"), Heritage Pharmaceuticals, Inc. ("Heritage"), Mylan Pharmaceuticals, Inc. ("Mylan"), and Mayne Pharma USA, Inc. ("Mayne").

I. INTRODUCTION AND NATURE OF THE ACTION

1. Generic pharmaceuticals – which are equivalent to brand name pharmaceuticals – have saved direct purchasers, consumers, and the American healthcare system tens of billions of dollars annually because generic pharmaceuticals typically introduce competition into a market where none previously existed. Typically, when a first generic pharmaceutical manufacturer enters a branded market, the generic pharmaceutical is priced slightly lower than the branded pharmaceutical. However, the appearance of a second generic pharmaceutical manufacturer reduces the average generic price to nearly half the brand price. As additional generic manufacturers enter the market, prices usually continue to fall. For branded products that attract a large number of generic manufacturers, the average generic price can fall to a small fraction of the branded price.

[1] As used herein, the term "doxycycline" or "doxy" will refer to generic doxycycline hyclate, including the delayed release ("Doxy DR") version of doxycycline hyclate, unless otherwise indicated. As used herein, the term "digoxin" is intended to refer to doses of generic digoxin taken orally in the form of a tablet or capsule.

2. Over the last several years, however, that price dynamic has changed for a large number of generic pharmaceuticals. Prices for dozens of generic pharmaceuticals have skyrocketed without legitimate economic reasons. These unusual price increases have sparked investigations by Congress, the U.S. Department of Justice Antitrust Division ("DOJ"), state attorney generals, and the media. These investigations have begun to reveal a reportedly broad, well-coordinated, and long-running series of schemes to fix prices, allocate markets, and rig bids for a number of generic pharmaceuticals in the U.S. These investigations have also revealed that collusion on generic pharmaceuticals was centered around trade associations, such as the Generic Pharmaceutical Association ("GPhA"), customer conferences, and other industry gatherings.

3. Digoxin and doxycycline are among the generic pharmaceuticals that have seen drastic price increases as a result of collusion. As alleged herein, defendants engaged in a conspiracy to allocate customers, rig bids and fix, maintain and/or stabilize the prices of generic digoxin and doxycycline.[2]

4. As a result of defendants' unlawful conduct, plaintiffs and the other members of the proposed direct purchaser class paid artificially inflated prices.

5. Plaintiffs seek to recover damages incurred by themselves and the class due to defendants' and co-conspirators' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an overarching scheme to eliminate competition for generic digoxin and doxycycline and to artificially inflate the prices of generic pharmaceuticals through unlawful agreements.

6. Plaintiffs make the allegations herein based on personal knowledge of these matters relating to themselves and upon information and belief as to all other matters.

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[2] As described in more detail below, digoxin is used to treat heart failure and doxycycline is an antibiotic used to treat a variety of conditions.

II. ONGOING GOVERNMENT INVESTIGATIONS

7. The DOJ's investigation of the generic pharmaceutical industry followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic pharmaceutical pricing. The NCPA's news release states:

> Pharmacy acquisition prices for many essential generic drugs have risen by as much as 600%, 1,000% or more, according to a survey of more than 1,000 community pharmacists conducted by NCPA. The same survey found that patients are declining their medication due to increased co-pays (or total costs for the uninsured) and that the trend has forced more seniors into Medicare's dreaded coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.
>
> Over the last six months I have heard from so many of our members across the U.S. who have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate," NCPA CEO B. Douglas Hoey, RPh, MBA wrote in a letter to the panels' respective leaders, Chairman Tom Harkin (D-Iowa) and Ranking Member Lamar Alexander (R-Tenn.) and Chairman Fred Upton (R-Mich.) and Ranking Member Henry Waxman (D-Calif.).[3]

8. NCPA's survey of community pharmacists found that 77% of pharmacists reported 26 or more instances during six months of 2013 alone with a large upswing in a generic drug's acquisition price.

9. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Representative Elijah E. Cummings sent letters to generic pharmaceutical companies including, defendants Actavis,

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[3] News Release, NCPA, *Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say* (Jan. 8, 2014), *available at* http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say.

Heritage, Lannett, Par, Sun, Impax, Mylan, and West-Ward (the "October Letters") asking for detailed information on various generic pharmaceutical price hikes, including generic digoxin and/or generic doxycycline price hikes.[4]

10. On November 20, 2014, a Senate committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?" (the "Senate Hearing"). Various witnesses discussed the price hikes for generic pharmaceuticals. Although Arthur Bedrosian, the CEO of Lannett, was invited to testify, neither he nor any other chief executive of a generic pharmaceutical manufacturer did so.[5]

11. By late 2014, as part of its ongoing investigation, the DOJ convened a grand jury in this District. This grand jury has issued subpoenas and other requests for information to various generic pharmaceutical manufacturers, including defendants Heritage, Mylan, Sun, Par, Impax, Mayne, Actavis, and Lannett.

12. According to a June 26, 2016 report by Policy and Regulatory Report ("PaRR Report"), the DOJ's investigation is focusing on trade associations and is wide-ranging:

> A PaRR source says prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department's largest criminal antitrust probe ever. Like in that case, prosecutors expect to "move from one drug to another in a similar cascading fashion."[6]

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[4] U.S. Senator Bernie Sanders Senate Website, *Congress Investigating Why Generic Drug Prices Are Skyrocketing* (Oct. 2, 2014), *available at* http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

[5] U.S. Senator Bernie Sanders Press Release, *Drugmakers Mum on Huge Price* Hikes (Nov. 20, 2014), *available at* http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes.

[6] Eric Palmer, *DOJ Criminal Probe Takes a Look at Trade Associations*, FiercePharma (July 10, 2015), *available at* http://www.fiercepharma.com/regulatory/doj-criminal-probe-takes-a-look-at-trade-associations.

13. On December 12 and December 13, 2016, the DOJ filed the first criminal charges stemming from its ongoing investigation. *See United States v. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa. Dec. 12, 2016 Dec. 12, 2016); *United States v. Malek,* No. 2:16-cr-00508-RBS (E.D. Pa. Dec. 13, 2016) (the "Heritage Indictments"). These cases are both pending in this District and allege that these former senior executives of generic pharmaceutical-maker Heritage (a defendant here) violated Section 1 of the Sherman Act by participating in conspiracies to fix prices, rig bids and allocate customers for, among other generic pharmaceuticals, generic Doxy DR. Glazer was the CEO and Chairman of Heritage. Malek was the Senior Vice President, Commercial Operations and later President of Heritage.

14. According to Count One of the Heritage Indictments, "[t]he charged combination and conspiracy consisted of a continuing agreement, understanding, and concert of action among the defendant and co-conspirators, the substantial terms of which were to allocate customers, rig bids, and fix and maintain prices for doxycycline hyclate sold in the United States." The Heritage Indictments allege that Glazer and Malek, along with co-conspirators, carried out the combination and conspiracy by engaging in anticompetitive conduct, including, but not limited to, allegations that they:

a. participated, directed, authorized, or consented to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to discuss the sale of doxycycline hyclate in the United States;

b. participated, directed, authorized, or consented to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to allocate customers or rig bids for doxycycline hyclate sold in the United States;

c. agreed during those meetings, conversations, and communications to allocate customers for doxycycline hyclate sold in the United States agreed during those meetings, conversations, and communications with co-conspirators not to compete against each other for certain customers for doxycycline hyclate sold in the United States;

d. submitted bids, withheld bids, and issued price proposals in accordance with the agreements reached;

e. sold doxycycline hyclate in the United States and elsewhere at collusive and noncompetitive prices; and

f. accepted payment for doxycycline hyclate sold in the United States at collusive and noncompetitive prices.

15. Evidence reportedly unearthed in a related case indicates that Glazer and Malek of Heritage specifically engaged in bid-rigging related to Doxy DR. Evidence also reportedly shows that Malek compiled a large list of generic pharmaceuticals and instructed employees to contact competitors, such as Mylan, to reach agreement to increase, fix and/or stabilize prices, allocate customers, and rig bids for various generic pharmaceuticals.

16. In addition to the ongoing DOJ investigation, in December 2016, the Attorneys General of 20 states filed a civil complaint in the U.S. District Court for the District of Connecticut against various generic pharmaceutical manufacturers, including defendants Heritage, Mayne, and Mylan, also alleging price fixing, market allocation, and bid rigging of generic pharmaceuticals, including Doxy DR (the "AG Complaint").[7] The AG Complaint states claims under Section 1 of the Sherman Act, 15 U.S.C. § 1. Prior to filing the AG Complaint, the plaintiff states, such as Connecticut, engaged in an investigation and served subpoenas on various generic pharmaceutical manufacturers, including many of the defendants here.

17. In addition to the antitrust violations identified in the AG Complaint, the AG Complaint states that "the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the

[7] Complaint, *Connecticut v. Aurobindo Pharma USA, Inc.*, 3:16-cv-2056-VLB, ECF No. 1 (D. Conn. Dec. 15, 2016). The plaintiff states include Connecticut, Delaware, Florida, Hawaii, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Nevada, New York, North Dakota, Ohio, Pennsylvania, Virginia, and Washington.

appropriate time."[8] The state attorneys general describe these conspiracies as "schemes to fix and maintain prices, allocate markets and otherwise thwart competition" and explain that they are carried out by generic companies through their senior executives who "exploit their interactions at various and frequent industry trade shows, customer conferences and other similar events, to develop relationships and sow the seeds for their illegal agreements. The anticompetitive agreements are further refined and coordinated at regular 'industry dinners', 'girls nights out', lunches, parties, and numerous and frequent telephone calls, emails and text messages."[9]

18. The Connecticut Attorney General's press release regarding the AG Complaint states, "[m]y office has dedicated significant resources to this investigation for more than two years and has developed compelling evidence of collusion and anticompetitive conduct across many companies that manufacture and market generic drugs in the United States."[10]

19. The Connecticut Attorney General's press release also states that "we have evidence of widespread participation in illegal conspiracies across the generic drug industry. Ultimately, it was consumers – and, indeed, our healthcare system as a whole – that paid for these actions through artificially high prices for generic drugs. We intend to pursue this and other enforcement actions aggressively, and look forward to working with our colleagues across the country to restore competition and integrity to this important market." The press release also

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[8] *Id.* at ¶ 9.

[9] *Id.* at ¶¶ 7-8.

[10] Press Release, State of Connecticut Attorney General George Jepsen, *Connecticut Leads 20 State Coalition Filing Federal Antitrust Lawsuit against Heritage Pharmaceuticals, other Generic Drug Companies*, (Dec. 15, 2016), *available at* http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

states that the AG Complaint was filed under seal and that "[p]ortions of the complaint are redacted in order to avoid compromising the ongoing investigations."

20. On January 9, 2017, Glazer and Malek pleaded guilty to conspiring to manipulate prices of a doxycycline hyclate between April 2013 and December 2015, as well as other generic pharmaceutical products.[11] At the plea hearing, DOJ prosecutors stated that the conspiracy also involved the Heritage executives' superiors and subordinates and that rival companies were also involved.[12] Glazer and Malek are scheduled for sentencing later this year.

21. Press reports have stated that Glazer and Malek are likely cooperating with the DOJ's ongoing investigation.[13] Robert Connolly, the former head of the DOJ Antitrust Division's Philadelphia field office commented on the prosecution of Glazer and Malek, stating: "[i]t sounds like it can be just the first case and others will follow . . . I would assume there is more to come."[14]

22. Plaintiffs may seek to further amend this complaint to add additional generic pharmaceuticals and defendants, including generic pharmaceuticals and defendants that currently are the subject of separately filed complaints.

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[11] Bill Wichert, *Ex-NJ Pharma Execs Admit to Generic Drug Price-Fixing Plot*, Law360 (Jan. 10, 2017), *available at* https://www.law360.com/competition/articles/879229/ex-nj-pharma-execs-admit-to-generic-drug-price-fixing-plot.

[12] Jeremy Roebuck, *Ex-N.J. Pharma Execs Admit to Fixing Generic Drug Prices*, Philly.com (Jan. 10, 2017), *available at* http://www.philly.com/philly/news/410194135.html.

[13] Nathan Verdi, *The Man The Feds Are Using to First Crack Open Their Big Antitrust Case Against Generic Drug Makers*, Forbes (Dec. 14, 2016), *available at* http://www.forbes.com/sites/nathanvardi/2016/12/14/the-man-the-feds-are-using-to-first-crack-open-their-big-antitrust-case-against-generic-drug-makers/#7ce70c7d6124.

[14] *Id.*

III. JURISDICTION AND VENUE

23. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 4 of the Clayton Act, 15 U.S.C. § 15. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

24. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22 and 28 U.S.C. § 1391(b) and (c) because during the Class Period (defined below), the defendants transacted business in the U.S., including in this District.

25. During the Class Period, defendants sold and shipped generic pharmaceuticals in a continuous and uninterrupted flow of interstate commerce, which included sales of generic digoxin and doxycycline in the U.S., including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the U.S., including in this District.

26. This Court has personal jurisdiction over each defendant because, *inter alia*, each defendant: (a) transacted business throughout the U.S., including in this District; (b) participated in the selling and distribution of generic digoxin and doxycycline throughout the U.S., including in this District; (c) had and maintained substantial contacts with the U.S., including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for generic digoxin and doxycycline that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the U.S., including in this District.

IV. PARTIES

A. Plaintiffs

27. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail pharmacies in the Northeast under the name Kinney Drugs, Inc.

KPH directly purchased generic digoxin and doxycycline from one or more of the defendants during the Class Period. As a result of defendants' antitrust conspiracy, KPH paid supracompetitive prices for its generic digoxin and doxycycline purchases and KPH was injured by the illegal conduct alleged herein.

28. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, New York 14624. RDC directly purchased generic digoxin and doxycycline from one or more of the defendants during the Class Period. As a result of defendants' antitrust conspiracy, RDC paid supracompetitive prices for its generic digoxin and doxycycline purchases and RDC was injured by the illegal conduct alleged herein.

29. Plaintiff César Castillo Inc. ("CCI") is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business located in Río Piedras, Puerto Rico. CCI directly purchased generic doxycycline and digoxin directly from one or more of the defendants during the Class Period. As a result of defendants' antitrust conspiracy, CCI paid supracompetitive prices for its generic digoxin and doxycycline purchases and CCI was injured by the illegal conduct alleged herein.

30. Plaintiff Ahold USA, Inc. is a Maryland Corporation with its principal places of business in Quincy, Massachusetts and Carlisle, Pennsylvania. Ahold purchased generic digoxin and doxycycline directly from one or more of the defendants during the Class Period. As a result of defendants' antitrust conspiracy, Ahold paid supracompetitive prices for its generic digoxin and doxycycline purchases and Ahold was injured by the illegal conduct alleged herein.

B. Defendants

31. Defendant Lannett Company, Inc. ("Lannett") is a Delaware corporation that has its principal place of business in Philadelphia, Pennsylvania. Lannett is a manufacturer and

distributor of generic digoxin, among other generic pharmaceuticals. Lannett primarily markets its generic pharmaceutical products to pharmaceutical wholesalers, retail drug chains, distributors, and government agencies. During the Class Period, Lannett sold generic digoxin to purchasers in this District and throughout the U.S.

32. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation that has its principal place of business in Hayward, California. Impax has facilities in New Jersey and Philadelphia. Impax's generics division is called Global Pharmaceuticals ("Global") and is a manufacturer and distributor of generic digoxin, among other generic pharmaceuticals. During the Class Period, Global sold generic digoxin to purchasers in this District and throughout the U.S.

33. Defendant Par Pharmaceutical, Inc. ("Par") is a New York corporation with its principal place of business in Chestnut Ridge, New York. In January 2014, Par announced that it had entered an exclusive supply and distribution agreement with Covis Pharma S.à.r.l. ("Covis") for Covis's Lanoxin (digoxin) tablets. Par then began selling and shipping 0.125 mg and 0.25 mg strengths of digoxin tablets in the U.S. Par also manufactures and distributes generic doxycycline, among other generic pharmaceuticals. During the Class Period, Par sold generic digoxin and doxycycline to purchasers in this District and throughout the U.S.

34. Defendant West-Ward Pharmaceuticals Corporation ("West-Ward") is a Delaware corporation with its principal place of business in Eatontown, New Jersey. West-Ward is the U.S. agent and subsidiary of Hikma Pharmaceuticals PLC ("Hikma"), a London based global pharmaceutical company, and is a manufacturer and distributor of generic digoxin and doxycycline, among other generic pharmaceuticals. Hikma's 2014 Annual Report stated that "[g]enerics and injectables revenue were $216 million and $713 million, respectively (2013:

$268 million and $536 million) including strong sales of doxycycline . . . ." During the Class Period, West-Ward sold generic digoxin and doxycycline to purchasers in this District and throughout the U.S.

35. Defendant Actavis Holdco U.S., Inc. ("Actavis") is a Delaware corporation and a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc. ("Teva USA"). Actavis Pharma, Inc. is a U.S. subsidiary of Actavis Holdco U.S., Inc. that sold generic drugs including doxycycline in the U.S. during the Class Period. Teva USA's parent company, Teva Pharmaceutical Industries Ltd. acquired the Actavis generics business (including Actavis Holdco U.S., Inc. and Actavis Pharma, Inc.) from Allergan plc in August 2016. Actavis manufactures and distributes generic doxycycline, among other generic pharmaceuticals. During the Class Period, Actavis sold generic doxycycline to purchasers in this District and throughout the U.S.

36. Defendant Sun Pharmaceutical Industries, Inc. ("Sun") is a Michigan corporation with its principal place of business in Cranbury, New Jersey. In late 2012, Sun acquired URL Pharma, Inc. ("URL") with its principal place of business in Philadelphia, PA. URL is a wholly-owned subsidiary of Sun. URL as a group includes five wholly-owned subsidiaries, including Mutual Pharmaceutical Company, Inc. In late 2012, Sun and its wholly-owned subsidiaries held approximately 19.9% of the market share of doxycycline hyclate in the United States. Since then, Sun has continuously manufactured and distributed various doses of doxycycline in the U.S., including: 20 mg tablets, 100 mg tablets, 100 mg capsules, and 50 mg capsules, among other generic pharmaceuticals. During the Class Period, Sun sold generic doxycycline and digoxin to purchasers in this District and throughout the U.S.

37. Defendant Heritage Pharmaceuticals, Inc. ("Heritage") is a Delaware corporation with its principal place of business in Eatontown, New Jersey. During the Class Period, Heritage

manufactured and sold generic doxycycline hyclate DR and in the U.S., among other generic pharmaceuticals. In April 2011, Heritage was acquired by Emcure Pharmaceuticals Ltd. ("Emcure"), based in Pune, India. As a subsidiary of Emcure, Heritage conducts Emcure's U.S. commercial operations. During the Class Period, Heritage sold generic doxycycline to purchasers in this District and throughout the U.S.

38. Defendant Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. It is a subsidiary of Mylan, Inc., a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania. In 2006, Mylan's ANDA applications for doxycycline tablets in doses of 50 mg, 75 mg, and 100 mg were approved with a 150 mg dose following soon after. In 2012, Mylan received final approval from the FDA for its ANDA for 150 mg doxycycline hyclate DR tablets, receiving 180 days of generic exclusivity. In 2016, Mylan continued its practice of releasing generic versions of Doxy DR by marketing both 200 mg and 50 mg versions of the drug after FDA approval. During the Class Period, Mylan sold generic doxycycline and digoxin to purchasers in this District and throughout the U.S.

39. Defendant Mayne Pharma USA, Inc. ("Mayne") is a Delaware corporation with its principal place of business in Raleigh, North Carolina. On July 9, 2013, Mayne Pharma announced the launch of Doxy DR tablets for sale in the U.S. in doses of 75 mg and 100 mg tablets. In early 2014, Mayne expanded their generic doxycycline portfolio by selling a 150 mg Doxy DR and later, in 2016, also selling 50 mg and 200 mg Tablets. On February 25, 2016, Mayne's half-year media release indicated "[t]he Company is confident it has the right team and strategies in place to protect the Doryx/doxycycline franchise in the event of generic competition

on the 200 mg tablet."[15] During the Class Period, Mayne sold generic doxycycline to purchasers in this District and throughout the U.S.

40. Defendants have engaged in the conduct alleged in this Complaint, and/or the defendants' officers, agents, employees, or representatives have engaged in the alleged conduct while actively involved in the management of defendants' business and affairs.

V. UNIDENTIFIED CO-CONSPIRATORS

41. Various other persons, firms, entities and corporations, not named as defendants in this complaint, have participated as co-conspirators with defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

42. The true names and capacities, whether individual, corporate, associate, or representative, is unknown to plaintiffs at this time. Plaintiffs may amend this complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.

43. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with defendants in their unlawful conduct as described herein.

44. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

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[15] Mayne Pharma, ASX Announcement (Feb. 26, 2016), *available at* https://www.maynepharma.com/media/1520/hy-16-media-release.pdf.

VI. FACTUAL ALLEGATIONS

A. Overview of Generic Pharmaceutical Market

45. Generic pharmaceuticals typically provide consumers with a lower-cost alternative to brand name pharmaceuticals while providing the same treatment. Specifically,

> A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.[16]

46. Further, "[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product."[17]

47. Generic versions of brand name drugs typically are priced significantly below the brand name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act

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[16] Drugs@FDA Glossary of Terms, U.S. Food & Drug Admin. (last visited Jan. 24, 2017), *available at* http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G.

[17] *Id.*

(Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282)).

48. Economic literature in the healthcare market has demonstrated that competition by generic products typically results in lower prices for consumers. In the period before generic entry, a brand name drug commands 100% of the market share for that drug and the brand name manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand name drug rapidly loses sales, as much as 80% or more by the end of the first year. As more generic manufacturers enter the market, prices for generic versions of a drug typically will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates as more generic options are available to purchasers.[18]

49. Indeed, both the price differential between the brand and its generic equivalents, and the proportion of the molecule sales captured by the generics, follow a predictable pattern. Specifically, the first generic competitor generally prices at a level of approximately 15% to 25% below the brand name price. As more A-rated generic products enter into the market, the prices of generics typically continue to decline both in absolute terms and in relation to the brand price, a trend that typically persists for five years, or more. Generic prices eventually reach as low as 10% to 20%, if not lower, of the pre-generic entry brand name price when an equilibrium, or market-clearing, price point is finally reached.[19]

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[18] *See, e.g.*, Ernst R. Berndt, *et al.*, *Authorized Generic Drugs, Price Competition, And Consumers' Welfare*, 26 Health Affairs 790 (2007).

[19] Stephen W. Schondelmeyer, Professor, Univ. of Minn. Coll. of Pharm., Testimony during hearing on *Why Are Some Drugs Skyrocketing in Price?*, before the U.S. Senate Committee on Health, Education, Labor and Pensions (Nov. 20, 2014) ("Schondelmeyer Statement"), *available at* http://www.help.senate.gov/imo/media/doc/Schondelmeyer.pdf.

50. This predictable pattern has been extensively studied and is generally accepted as an inherent feature of the pharmaceutical industry.[20]

51. Generic competition thus enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name drug, and/or (b) purchase the brand name drug at a reduced price. Generic competition to a single branded drug product can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.

52. Drug companies that want to introduce a generic drug to the market file an Abbreviated New Drug Application ("ANDA") with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. The filing is called "abbreviated" because the ANDA sponsor references data submitted in the approval of the Reference Listed Drug ("RLD") (the brand name drug). "By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart."[21] An ANDA sponsor is generally not required to include clinical trial data to establish the safety and efficacy of the drug. Instead, a generic drug company must show that its generic product is "bioequivalent" to the name brand drug,[22] *i.e.*, the generic product and the brand RLD have the same (i) active ingredient, (ii) maximum amount of drug in the blood at a given time, (iii) total amount of drug in the blood over time, (iv) strength, dosage, dosage form, (v) expected safety and efficacy, and (vi) FDA approval of manufacturing facilities. Upon the FDA's determination that

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[20] *Id.* at 13-14, figures 5-7, and n. 10.

[21] Drugs@FDA Glossary of Terms, U.S. Food & Drug Admin. (last visited Jan. 24, 2017), *available at* http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G.

[22] *Id.*

bioequivalence has been established, the ANDA applicant may manufacture and market its generic drug in the U.S. as interchangeable with the RLD.

53. Generic drugs that are bioequivalent to an RLD are assigned a Therapeutic Equivalence Code ("TE Code").[23] An oral generic drug product will be coded "AB" if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA's evaluations.[24]

54. Although generic drugs are widely understood to be substantially cheaper than their branded counterparts, for the drugs at issue here, that is no longer the case.

B. Pricing of Generic Pharmaceuticals

55. The FDA has recognized that "[g]eneric competition is associated with lower drug prices[.]"[25] A Federal Trade Commission study reached the same conclusion, finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[26] Defendants recognize this as well. For example, a May 2015 presentation by defendant Lannett CEO Arthur Bedrosian and CFO Marty Galvan, noted that generic pharmaceuticals often cost "80-85% less than the brand."[27]

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[23] *Id.*

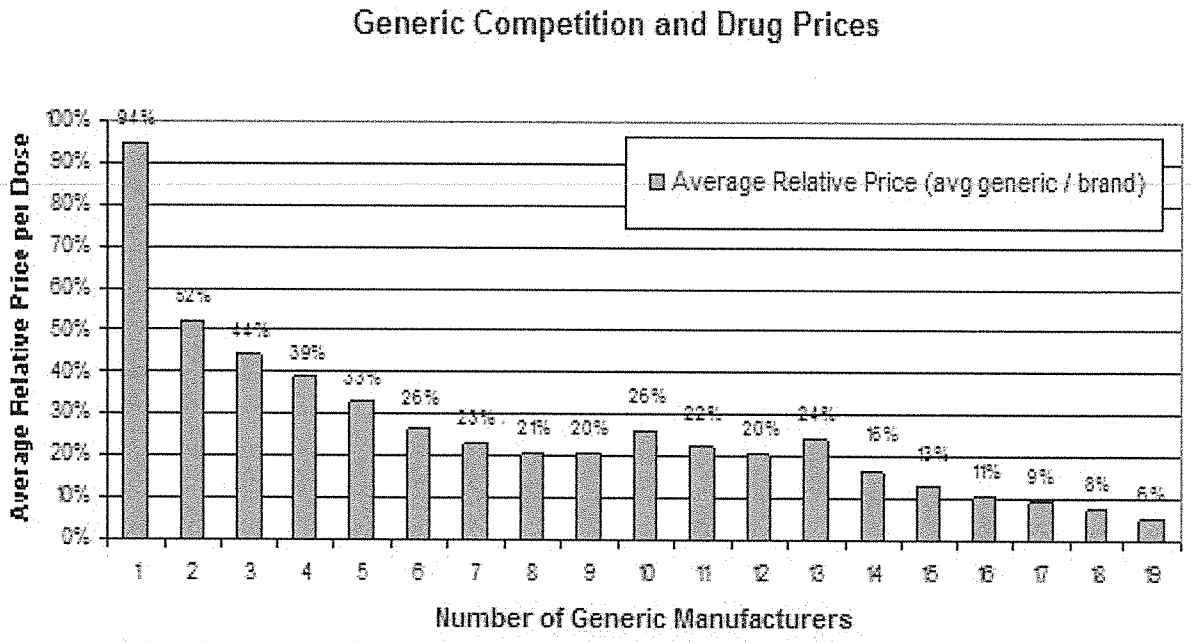
[24] *Id.*

[25] Generic Competition and Drug Prices, U.S. Food & Drug Admin. (last visited Jan. 24, 2017), *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

[26] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff.

[27] Lannett PowerPoint Presentation, at 3 (May 2015).

56. FDA analysis confirms that as more generic manufacturers enter the market, prices for generic versions of a drug will continue predictably to fall:



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

57. A mature generic market, such as the markets for doxycycline and digoxin, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.[28] Over time, generics' pricing nears the generic manufacturers' marginal costs.

58. The pricing of prescription pharmaceutical products in the U.S. is governed by institutional features typically not present in the marketplace for other consumer products.

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[28] *See, e.g.*, FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."); U.S. Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

59. Ordinarily, the price for a consumer product is set by the retailer based on the amount the typical consumer is willing to pay. Because of the unique features of the prescription drug marketplace, however, pricing of prescription drugs for most consumers is not determined between the retailer and the consumer. Rather, because most consumers' prescription drug purchases are reimbursed by public or private health plans, the pricing for prescription drugs is determined by reimbursement agreements between these prescription drug payors, *i.e.*, health plans and their prescription benefit managers, and the pharmacies that dispense drugs to the payors' insured consumers.

60. At one time, payors relied on cost-based pricing metrics to reimburse pharmacies that dispensed drugs to their insured consumers, paying the dispensing pharmacies an amount based on the manufacturer's list price for the drug, plus a small mark-up and/or dispensing fee. Over time, however, it was learned that the list price for most generic drugs published by their manufacturers was substantially higher than the actual cost incurred by pharmacies to acquire the drugs.

61. To reduce the cost of prescription drugs to the public, prescription drug payors developed Maximum Allowable Cost prices ("MACs") to determine the amount that pharmacies would be reimbursed for dispensing generic pharmaceuticals. The MAC price refers to the maximum amount that a payor will reimburse a pharmacy for a given strength and dosage of a generic drug or brand name drug that has a generic version available. A MAC price thus represents the upper limit that a prescription drug payor will pay a pharmacy for a generic drug.

62. Payors set the MAC price of a drug based on a variety of factors, including, most significantly, the lowest acquisition cost for each generic drug paid by retail pharmacies purchasing from a wholesaler for each of a drug's generic versions.

63. MAC pricing is designed to incentivize pharmacies to purchase the least costly version of a generic drug available in the market, without regard to the manufacturer's list price. Because the reimbursement amount to a pharmacy is limited by the MAC price for a generic drug and each of its equivalents regardless of the pharmacy's acquisition cost, a pharmacy's profit will be reduced, or lost altogether, if it purchases other than the lowest cost generic product. Alternatively, if a retail pharmacy purchases the lowest priced generic version of the drug, it will maximize its profit.

64. MAC pricing also incentivizes an individual generic manufacturer to refrain from unilaterally increasing its prices. Because MAC pricing bases reimbursement on the generic drug's lowest acquisition cost, a generic manufacturer that increases its price for a drug while competing manufacturers do not will swiftly lose sales to a competing generic manufacturer whose price remains constant.

65. Consequently, in the absence of coordinated pricing activity among generic manufacturers, an individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales.

C. Generic Digoxin and Pricing Information

66. Generic digoxin is a prescription drug used to treat heart failure and atrial fibrillation. Digoxin is a purified cardiac glycoside derived from *digitalis lanata*, or the foxglove plant, and was first described in medical literature in 1785. The World Health Organization ("WHO") includes digoxin on its list of essential medicines.

67. Digoxin has been available in the U.S. for over twenty years and the market for generic digoxin is mature. Because the market is a mature one, the products should behave like commodities, competing essentially solely on price and pricing near marginal costs.

68. On September 30, 1993, GlaxoSmithKline ("GSK") filed an NDA for the approval of digoxin tablets, under the brand name Lanoxin. GSK's NDA sought and received FDA approval of 0.125 mg and 0.250 mg doses of digoxin. Swiss drug manufacturer Covis purchased the rights to Lanoxin and several other GSK branded drugs on December 22, 2011. On April 1, 2015, Covis and its assets—including its rights to Lanoxin—were acquired by Concordia Healthcare Corp. ("Concordia") in an all-cash deal.

69. One of the first generics to file an ANDA in connection with generic Lanoxin was Amide Pharmaceuticals, Inc. ("Amide"). Amide filed ANDA 040282 on October 21, 1997, seeking approval for digoxin tablets. The FDA granted final approval on December 23, 1999. Amide and Mylan—through Mylan's wholly-owned subsidiary Bertek Pharmaceuticals—entered into a distribution agreement, whereby Mylan distributed Amide's approved digoxin tablets under the name "Digitek."

70. The next generic company to file an ANDA for generic Lanoxin was Jerome Stevens. Jerome Stevens filed ANDA 76268 on October 29, 2001, seeking approval for digoxin tablets. The FDA granted final approval on July 26, 2002. In March 2004, Jerome Stevens entered into a 10-year exclusive distribution agreement with Lannett, whereby Lannett became the exclusive seller of Jerome Stevens' digoxin tablets. In August 2013, this exclusive distribution deal was renewed for another five years.

71. At least four other manufacturers began selling generic digoxin tablets after Lannett, including: (a) Sun, which received approval for ANDA 076363 on January 31, 2003; (b) West-Ward, which received approval for ANDA 077002 on October 30, 2007; (c) Impax, which received approval for ANDA 078556 on July 20, 2009; and (d) Par, which began selling on January 16, 2014, with an authorized generic version of Lanoxin.

72. As of 2002, there were eight manufacturers of digoxin tablets. However, in the years since, the number of digoxin tablet manufacturers has decreased, making the market ripe for collusion.

73. Mylan, which still lists Digitek as one of its products, temporarily stopped selling digoxin tablets in or around April 2008. Mylan continued to maintain an active ANDA for the product. According to the National Average Drug Acquisition Cost ("NADAC") survey conducted the Centers for Medicare and Medicaid Services ("CMS"), Mylan returned to selling digoxin tablets in or around early 2015.

74. Similarly, in March 2009, Sun's subsidiary, Caraco, withdrew certain lots of digoxin tablets. Sun began selling digoxin in or around April 2015.

75. West-Ward also ceased manufacturing of all product lines, including digoxin, at its Eatontown, New Jersey facility temporarily in the beginning of 2013. West-Ward resumed manufacturing digoxin tablets at its Eatontown facility in July 2013.

76. In March 2014, Lannett entered a supply agreement with Jerome Stevens for the exclusive distribution rights in the U.S. for generic digoxin and two other drugs.

77. Lannett's 0.125 mg and 0.25 mg generic digoxin strength tablets have a TE Code of AB and are therapeutic equivalents to the Lanoxin 0.125 mg and 0.25 mg tablets.

78. Lannett's reported sales of generic digoxin from its 10-Ks were $12.4 million in 2011; $10.9 million in 2012; $11.7 million in 2013; and $54.7 million in 2014.

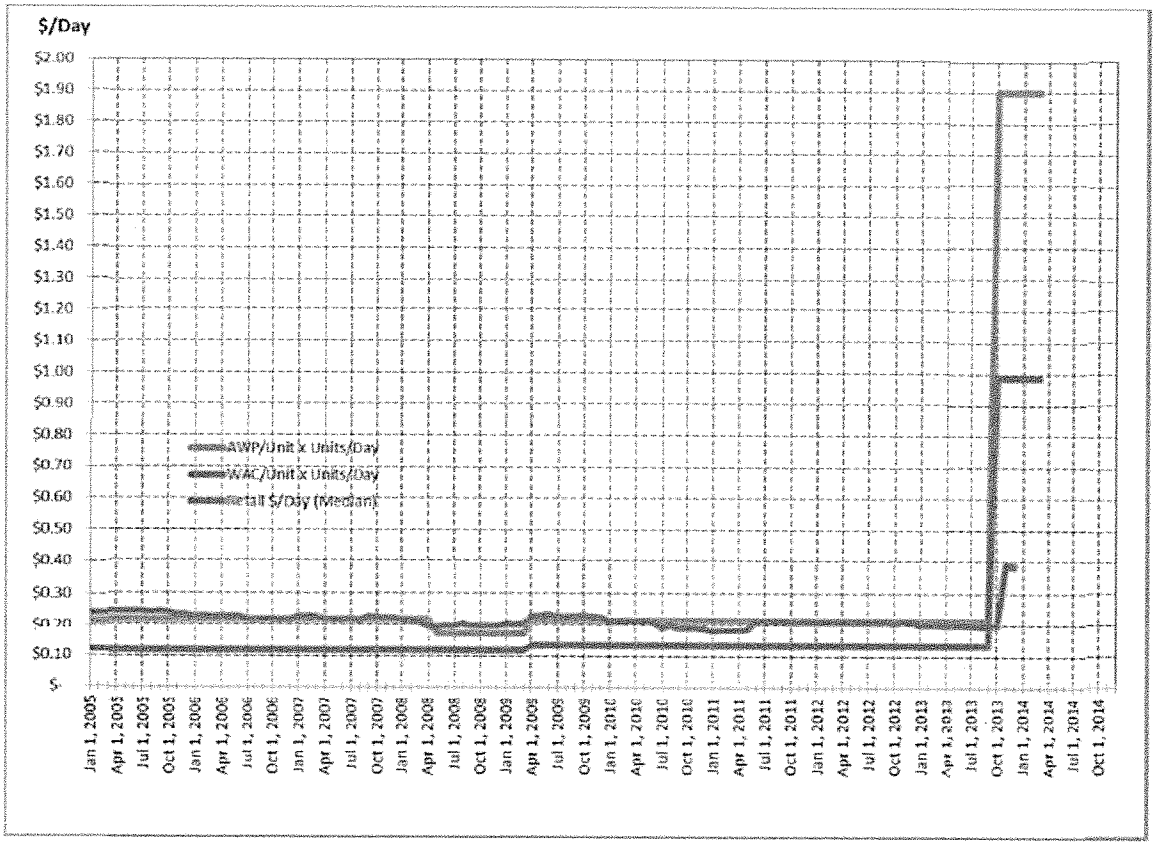
79. As a result of the withdrawals from selling digoxin by other manufacturers, Lannett and Impax controlled the market for generic digoxin through 2013, until Covis began making an authorized generic for digoxin, which is distributed by Par.

80. Annual sales of digoxin in the U.S. were approximately $44 million at the beginning of 2014 and rose sharply in 2014 and 2015.

81. Until mid-October 2013, pricing of generic digoxin was stable. However, prices subsequently increased sharply without justification by at least Lannett, West-Ward (when it re-entered), and Impax, followed by price increases by Par upon entering the market with an authorized generic in 2014, and by Mylan upon re-entering the market in 2015.

82. The following chart prepared by Dr. Stephen Schondelmeyer, Director of PRIME Institute at the College of Pharmacy at the University of Minnesota, was included in testimony before the U.S. Senate and shows the dramatic and unusual price increase for digoxin:

Figure 12. Digoxin 0.25 mg Tablet (Lannett) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)



The terms "AWP" and "WAC" in this chart refer, respectively, to "Average Wholesale Price" and "Wholesale Acquisition Price." Both prices are referred to by Dr. Schondelmeyer as benchmark prices.[29] Dr. Schondelmeyer's testimony provided valuable insight into the defendants' alleged price coordination and collusion.[30] Dr. Schondelmeyer noted that generic drug prices were rising above and beyond the rate of general inflation at a rate of 12.9% versus 1.5%.[31]

83. In or about November and December of 2013, pricing for 0.125 mg and 0.25 mg digoxin tablets increased by more than 750% from $.11 and $.12 per tablet to $.91 and $1.01 per tablet. Another price increase occurred between December 2013 and January 2014 from $1.08 to $1.11 per digoxin tablet.

84. Overall, according to NADAC data, the average price for generic digoxin increased over 900% from October 2012 to June 2014.[32]

85. The below chart demonstrates the steep increase in price of digoxin 0.125 mg (or 125 mcg) tablets in the latter part of 2013 and continuing into 2014.[33]

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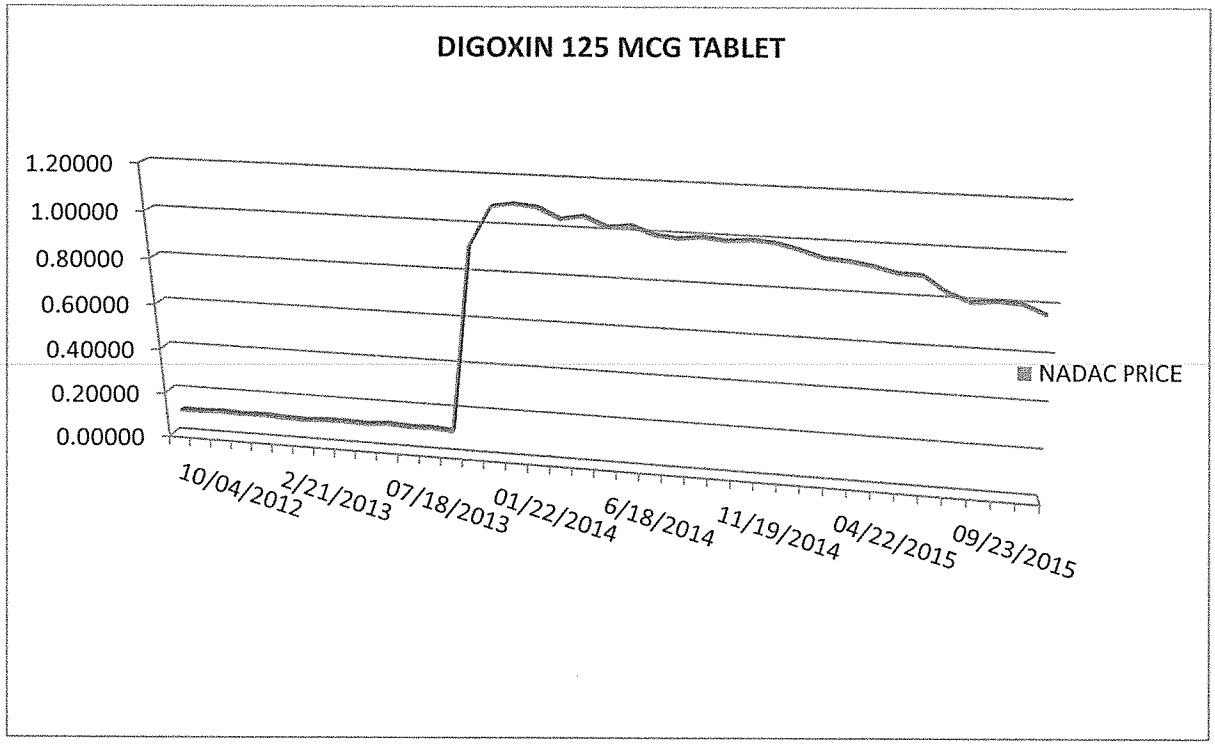
[29] Schondelmeyer Statement.

[30] *Id.*

[31] *Id.*

[32] *See* Correspondence to Arthur P. Bedrosian, President and Chief Executive Officer of Lannett, from Senator Bernie Sanders and Congressman Elijah Cummings, (Oct. 2, 2014), *available at* http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file.

[33] For raw data, *see* Nat'l Avg. Drug Acquisition Costs, Medicaid.gov (last visited Jan. 24, 2017), *available at* https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html.



86. During much of the Class Period, there were at least three or more separate manufacturers of generic digoxin. Under the well-accepted economics of generic competition, when there are that many generic versions of a drug available, all of which by definition are equally substitutable, prices should remain at highly competitive, historic levels, and would not increase as they did here, absent anticompetitive conduct.

87. Despite the entry of new competitors Par and Mylan in 2014 and 2015, however, digoxin prices remained supracompetitive as a result of defendants' unlawful conduct. In a competitive generic market, prices would be expected to decrease upon the entry of Par and Mylan. As indicated in a recent U.S. Government Accountability Office ("GAO") report:

> Additionally, manufacturers said that if a company is bringing a generic drug into an established drug market, it typically offers a price that is lower than the current market price in order to build its customer base. Manufacturers also said that as each new manufacturer enters an established generic drug market the price of that

generic will fall, with one manufacturer noting that it is typically a 20 percent price decline per entrant. As long as manufacturers continue to enter the market, generic drug prices continue the general downward trend.[34]

88. There were no competitive justifications for the abrupt and dramatic increase in prices.

89. No potential drug shortages explain the price increases. Title IX of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA") requires mandatory drug shortage reporting for drug manufacturers. None of the defendants reported any drug shortages to the FDA in explanation for the supracompetitive pricing of digoxin.

90. The American Society of Health System Pharmacists ("ASHP") also maintains a database of drug shortages, called the ASHO Drug Shortages Resource Center.[35] ASHP reported no current or unresolved drug shortages for digoxin tablets or capsules.

91. The presence or absence of competitors in the marketplace also does not explain the price of generic digoxin. From at least October 2012 until around November 21, 2013, the price for generic digoxin as reported in the NADAC data was consistently around $0.11 for the 0.125 mg tablets and between $0.11 and $0.12 for the 0.25 mg tablets. The chart presented by Dr. Schondelmeyer (reproduced above) confirms this. This was the case even though for a portion of that period after West-Ward suspended production, Lannett and Impax were the only significant sellers of digoxin. West-Ward returned in July of 2013, but pricing still remained stabilized for several months. Indeed, throughout 2012 and through September of 2013, as Dr. Schondelmeyer's chart shows, the price of generic digoxin remained steady. Following the

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[34] U.S. Gov't Accountability Office, *Generic Drugs Under Medicare*, at 23 (Aug. 2016), *available at* http://www.gao.gov/products/GAO-16-706.

[35] http://www.ashp.org/menu/DrugShortages.

astronomical price increases in the fall of 2013, Par entered in early 2014 and Mylan entered in 2015. Prices did not fall *despite the new competitors*. Pricing has remained inflated to this day.

92. On July 8, 2014, the New York Times reported that with respect to rapid price increases of generic pharmaceuticals, "[d]igoxin provides a telling case study. There was no drug shortage, according to the Food and Drug Administration that might explain the increase. There was no new patent or new formulation. Digoxin is not hard to make. What had changed most were the financial rewards of selling an ancient, lifesaving drug and company strategies intended to reap the benefits."[36]

93. Lannett claimed that factors influencing price increases included "problems acquiring raw material, increased costs of complying with Food and Drug Administration requirements and manufacturers exiting the market."[37] However, as noted by the Generics and Biosimilars Initiative on August 29, 2014, "[s]hortly after the arrival of Covis, the price of digoxin began to climb. It is not clear which company started this, however, the price doubled in six months. At the time of the price increases, the US Food and Drug Administration had reported no drug shortages, there was no new patent or new formulation and digoxin is not difficult to make. The companies have not yet provided an explanation for the price rise."[38]

94. Defendants' sudden and massive price increases represented a sharp departure from the previous years of stable prices.

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[36] Elisabeth Rosenthal, *Rapid Price Increases for Some Generic Drugs Catch Users by Surprise*, N.Y. Times (July 8, 2014), *available at* http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html?emc=eta1&_r=0.

[37] *Id.*

[38] Generics and Biosimilars Initiative, *Lawyers Look at New Price Hike for Old Drug* (Aug. 29, 2014), *available at* http://www.gabionline.net/layout/set/print/content/view/full/3437.

95. The steep digoxin price hikes have had a catastrophic effect on consumers. According to a December 2013 report:

> Bill Drilling, an owner of a pharmacy in Sioux City, Iowa, apologizes as he rings up a customer's three-month supply of the heart medicine digoxin. The total is $113.12—almost 10 times the cost for the same prescription in August. Digoxin isn't a new miracle drug. . . . "I've been doing this since 1985, and the only direction that generics-drug prices have gone is down," Drilling says.
>
> "This is starting to create hardship," he says. Many of his customers fall into what is known as the Medicare "doughnut hole," a coverage gap in which patients pay 47.5 percent of branded-drug costs and 79 percent of a generic's price. Russ Clifford, a retired music teacher, learned digoxin's cost had jumped more than fourfold when he picked up his 30-day supply in mid-November. Clifford and his wife have had to dip into savings to pay their rising pharmaceutical bills.[39]

D. Generic Doxycycline Market and Pricing Information

96. Generic doxycycline is a tetracycline antibiotic prescribed to patients for the treatment of a variety of bacterial infections, including acne, urinary tract infections, eye infections, Lyme disease, intestinal infections, sexually-transmitted diseases, and gum disease, among others. Doxycycline monohydrate has been prescribed since 1967 and is also listed as an essential medicine by WHO. Doxycycline hyclate is a variation of doxycycline monohydrate and entered the market in 1985. Doxy DR is a delayed release form of doxycycline hyclate.

97. Doxycycline has been available in the U.S. for decades and the market for generic doxycycline is mature. As a result, the products should behave like commodities, competing essentially solely on price and pricing near marginal costs.

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[39] Alan Katz, *Surprise! Generic Drug Prices Spike*, Bloomberg (Dec. 12, 2013), *available at* https://www.bloomberg.com/news/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise.

98. Actavis, Par, West-Ward, Mylan, and Sun primarily operate in the market for generic doxycycline. Mylan, Mayne, and Heritage primarily operate in the market for Doxy DR.

99. Branded versions of doxycycline hyclate are produced by Pfizer Inc., among others. Pfizer developed and manufactured Vibramycin and Vibra-Tabs. Vibramycin is a capsule form of doxycycline hyclate. Vibra-Tabs is a tablet form of Vibramycin. Pfizer received FDA approval for Vibramycin (NDA 050007) on December 5, 1967 and received FDA approval for Vibra-Tabs (NDA 050533) on January 15, 1980. Later, Pfizer withdrew Vibra-Tabs from the market. However, the FDA determined that Pfizer's withdrawal of Vibra-Tabs was not for reasons of safety or effectiveness, meaning that all existing generic versions could remain on the market.

100. Actavis manufactures generic versions of Vibramycin, Vibra-Tabs, and Monodox (capsule form). Actavis's generic version of doxycycline first entered in 1982.

101. Mylan manufactures generic versions of Vibra-Tabs. Mylan's generic versions of doxycycline hyclate first entered in 1982. Mylan also manufactures generic versions of Doxy DR.

102. Par manufactures and sells generic versions of doxycycline.

103. Sun manufactures generic versions of Vibramycin, Vibra-Tabs, and Monodox (capsule form).

104. West-Ward manufactures generic versions of Vibramycin and Vibra-Tabs. West-Ward launched its generic versions of doxycycline in 2003.

105. Heritage entered the market for Doxy DR on July 2, 2013. The only other generic manufacturer selling Doxy DR at that time was defendant Mylan.

106. Mayne entered the market for Doxy DR in February 2014.

107. At one point there were over 20 manufacturers of generic doxycycline. However, over the past decade, the number of generic pharmaceutical manufacturers producing doxycycline has steadily dropped. Major Pharmaceuticals, Teva Pharmaceuticals, and West-Ward were among the generic manufacturers that discontinued certain doxycycline product lines. Major Pharmaceuticals' and Teva Pharmaceuticals' discontinuations occurred in or around February 2013 and May 2013, respectively. West-Ward discontinued one line of doxycycline in or around July 2013.

108. This reduction in the number of generic manufacturers increased concentration among sellers of doxycycline, facilitating price coordination and defendants' conspiracy to fix, raise, maintain, and stabilize prices.

109. Retail sales in the U.S. of doxycycline in 2013 were estimated to be over $972 million.[40]

110. According to an October 2014 U.S. Senate fact sheet on generic pharmaceutical price increases, the average market price of doxycycline hyclate (bottle of 500, 100 mg tablets) increased from $20.00 in October 2013 to $1,849.00 in April 2014, an average percentage increase of 8,281%.[41]

111. For example, West-Ward's AWP pricing for generic doxycycline went from under $2.50 per day for 100 mg doxycycline hyclate capsule therapy to over $11 per day by

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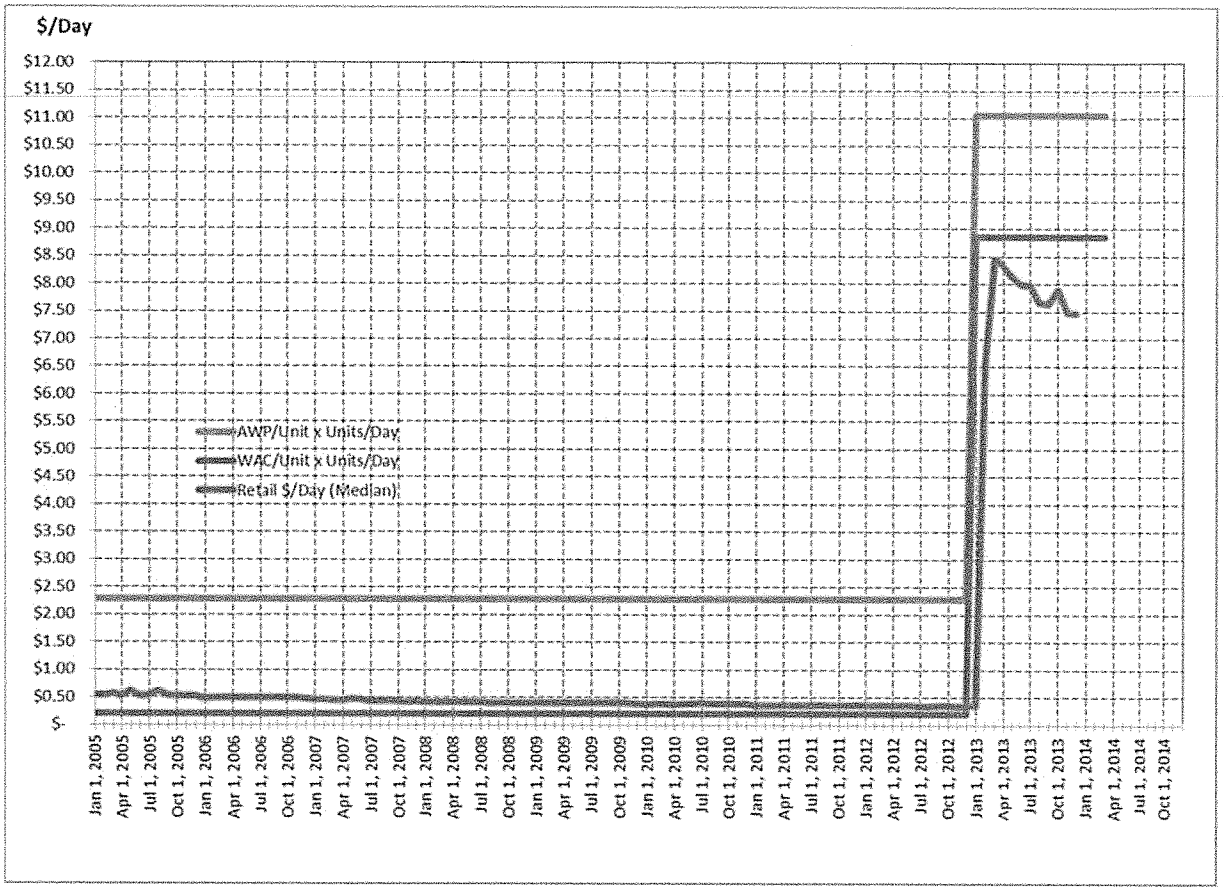
[40] Doxycycline Sales Data, Drugs.com (last visited Jan. 24, 2017), *available at* http://www.drugs.com/stats/doxycycline.

[41] U.S. Senator Bernie Sanders Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs (*Oct. 2, 2014), *available at* http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file.

January 2013, as demonstrated by the below chart, presented by Dr. Schondelmeyer in his testimony at the Senate Hearing:[42]

Figure 11. Doxycycline Hyclate 100 mg Capsule (West-Ward) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)



112. At all times during the Class Period, there were at least three or more separate manufacturers of generic doxycycline. Under the well-accepted economics of generic competition, when there are that many generic versions of a pharmaceutical available, all of which by definition are equally substitutable, prices should remain at highly competitive, historic levels, and would not increase as they did here, absent anticompetitive conduct.

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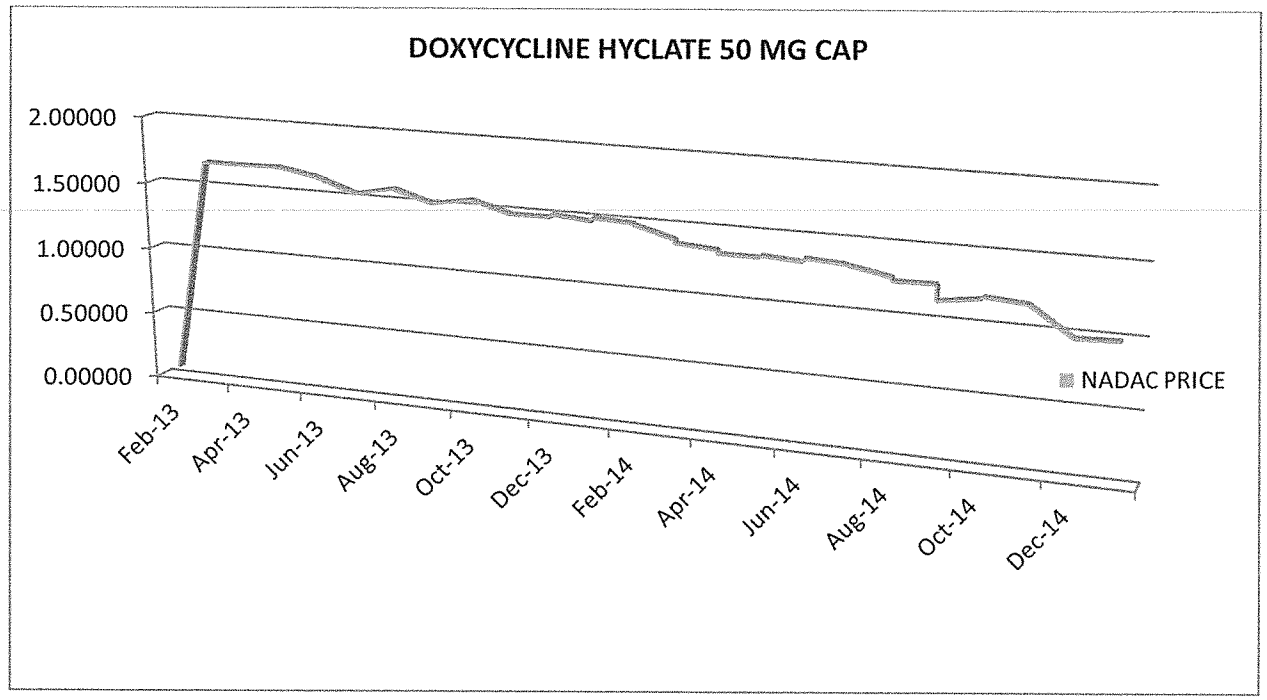
[42] *See* Schondelmeyer Statement.

113. The below chart demonstrates the steep increase in price of doxycycline hyclate 50 mg capsules in April 2013 and the continued elevated pricing through 2015.[43]



114. The NADAC data demonstrate that: (1) prices for doxycycline hyclate 100 mg capsules (*i.e.*, generic Vibramycin 100 mg capsules) have increased over 2,400% from their October 2012 prices; (2) prices for doxycycline hyclate 50 mg capsules (*i.e.*, generic Vibramycin 50 mg capsules) have increased nearly 1,800% from their October 2012 prices; (3) prices for doxycycline hyclate 100 mg tablets (*i.e.*, generic Vibra-Tabs 100 mg tablets) have increased over 3,100% from their October 2012 prices; and (4) prices for 75 mg and 100 mg Doxy DR tablets were maintained at supracompetitive levels.

115. There were no competitive justifications for the abrupt and dramatic increase in prices.

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[43] For raw data, *see* Nat'l Avg. Drug Acquisition Costs, Medicaid.gov (last visited Jan. 24, 2017), *available at* https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html.

116. No potential drug shortages explain the price increases.

117. Input costs do not explain these price hikes. Sun reported in a May 28, 2012 earnings call that "[m]aterial cost, as a percentage of the net sales is 18.5% which is lower as compared to the previous year." Likewise, in a November 14, 2013 earnings call, Sun reported that second quarter costs were "in-line with Q2 last year." Hikma, the parent of West-Ward, reported in 2013 that doxycycline sales reflected "exceptional profitability" and "generated exceptionally strong cash flows."

118. Defendants' sudden and massive price increases represented a sharp departure from the previous years of stable prices.

119. These price hikes caused extreme hardship to consumers. As reported on WSMVTV of Nashville's website in March of 2013:

> Many people may not recognize the name, but they have probably used it for a health problem at one point.
>
> Doctors use doxycycline to treat a wide range of issues, including everything from acne to Lyme disease, anthrax exposure and even heartworm in our pets.
>
> However, the once cheap and effective drug has now dramatically gone up in price, and that has health professionals concerned.
>
> Hospitals like Vanderbilt University Medical Center keep doxycycline in stock, but some folks worry the cure for their ailment could now be financially out of reach.
>
> "It's a change that occurred overnight," said Vanderbilt pharmacy manager Michael O'Neil.
>
> Not long ago, the pharmacy at Vanderbilt's hospital could purchase a 50-count bottle of 100 mg doxycycline tablets for $10, but now the same bottle costs a staggering $250.
>
> "That's concerning to us, both as citizens and practitioners, when you see a huge increase like this in a price of a drug," O'Neil said.

> Vanderbilt keeps thousands of doxycycline pills on hand in the event of a bioterrorist attack, like anthrax, and O'Neil said replacing expired pills is prohibitive.
>
> "This one is just hurting us when we need to replace the medication," he said.
>
> But it's the most vulnerable who are in the most jeopardy. For a pet, a heartworm diagnosis can be a death sentence without doxycycline.
>
> Veterinarian Dr. Joshua Vaughn of the Columbia Hospital for Animals is already seeing the tragic results.
>
> "We had one patient who we diagnosed with heartworm. We recommended heartworm treatment, but when they saw the total dollar amount, they elected not to treat the dog at all," Vaughn said.
>
> While manufacturers say they are having problems with raw supply, many in the medical community see greed as an overriding factor.
>
> Vaughn said he wrote a recent prescription for doxycycline that cost $77. This week, the price increased to nearly $3,000.[44]

E. Defendants' Anticompetitive Activities

120. Plaintiffs allege that during the Class Period, defendants conspired, combined, and contracted to fix, raise, maintain, and stabilize prices at which generic digoxin and generic doxycycline would be sold, allocate markets, and rig bids. As a result of defendants' unlawful conduct, plaintiffs and the other members of the proposed class paid artificially inflated prices that exceeded the amount they would have paid if a competitive market had determined prices for generic digoxin and generic doxycycline.

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[44] Alan Frio, *Sudden Increase in Cost of Common Drug Concerns Many*, WSMV-TV, *available at* http://www.wsmv.com/story/21616095/sudden-increase-in-cost-of-common-drug-concerns-many.

1. Annual Reports and Investor Communications

121. Defendants' statements and admissions in their annual reports and other investor communications emphasize the goal of and commitment to increasing generic pharmaceutical prices and maintaining them at supracompetitive levels. Additionally, evidence made public in ongoing investigations shows direct evidence of collusion.

a. Lannett

122. According to Lannett's 2014 annual report, digoxin accounted for 20% of Lannett's fiscal 2014 net sales and 8% of Lannett's 2013 fiscal net sales.

123. On September 10, 2013, Lannett's Chief Executive Officer, Arthur P. Bedrosian, stated in a fourth quarter earnings call that:

> We're not a price follower. We tend to be a price leader on price increasing and the credit goes to my sales vice president. He takes an aggressive stance towards raising prices. He understands one of his goals, his objectives as a sales vice president is to increase profit margins for the company. And he's the first step in that process. I can reduce costs and manufacturing efficiencies, but it has to be combined with sales increase, a profit increase, as I should say, by the salespeople. And he's done a good job there. With 1 or 2 exceptions, we've tended to lead in the way of price increases. We believe that these prices are important. We need to try raising them. Sometimes, it doesn't stick and we have to go back and reduce our price, and other times it does. I am finding a climate out there has changed dramatically and I see more price increases coming from our competing – competitors than I've seen in the past. And we're going to continue to lead. We have more price increases planned for this year within our budget. And hopefully, our competitors will follow suit. If they don't, that's their issue. But our plan is to raise prices on any product that we think we can or we haven't raised a price.

124. Bedrosian further described his expectation that other generics would also raise prices. After citing costs applicable to all generic firms, he stated that "I would expect that all the companies are not going to behave like they have in the past. And I suspect you're going to

see more price increases in the generic marketplace or certainly less price erosion in the marketplace because of that."

125. In addition Bedrosian noted, "I'm always grateful to see responsible generic drug companies realize that our cost of doing business is going up as well . . . [s]o whenever people start acting responsibly and raise prices as opposed to the typical spiral down of generic drug prices, I'm grateful. Because Lannett tends to be active in raising prices. We believe we have to sell our products for a price that we can make profit. . . . So I'm grateful to see price increases."

126. In a subsequent earnings call, Bedrosian reported that Lannett's chief competitor had indeed heeded its price increase signal. In a first quarter 2014 earnings call on November 7, 2013 – after the initial generic digoxin price increases – Bedrosian noted, referring to Impax, that "[w]e've had a recent price increase on the [generic digoxin] product as well because we are now only 1 of 2 people in the market. And as a result, I expect that product to do very well."

127. In the same first quarter 2014 earnings call, Bedrosian was confident enough that its price increases would hold to increase Lannett's next quarter guidance stating, "[t]he primary drivers for our outstanding first quarter performance was a combination of strong sales of existing products, a favorable product mix and price increases on key products. I'm pleased to report that we believe these positive trends will continue throughout fiscal 2014. Accordingly, we have raised our guidance for fiscal 2014."

128. Bedrosian also reiterated Lannett's "[i]ncrease in the guidance, probably a significant portion is the price increases that we've talked about previously that have now really hit us in a beneficial way." Bedrosian indicated that he believed Lannett's growth margin was sustainable, notwithstanding the fact that they are in a commodity market, reflecting confidence that his competitors were committed to the conspiracy and would hold to their higher prices, "I

would believe they are sustainable because we're not expecting any changes that we anticipate at this point. But we're in the commodity business, so it's always hard to determine point when you're going to get additional competition or when prices will erode as they generally do." Mr. Bedrosian also indicated that the price increases were industry-wide and that he believed all generic companies would continue to adhere to higher prices: "So these price increases that are going on in the industry, I think they're going to stick for all the companies."

129. In a February 6, 2014 earnings call for Lannett's second quarter of 2014, Bedrosian reported that he was not troubled by Par's pricing in after Par launched generic digoxin and that he viewed Par to be "one of our rational competitors in the marketplace." Lannett's sales reported in February 2014 were the best in the company's history, and Lannett was able to increase its profit guidance on the strength of the price increases. As predicted in November 2013, Bedrosian reported that these record sales were driven by "price increases on key products, strong sales of existing products and favorable product mix." Lannett's stellar performance is not reflective of a company that took price increases that were forced by rising costs, but instead is reflective of a company that was enjoying the fruits of supracompetitive prices and stifling of competition. On the same call, Lannett's CFO Martin P. Galvan also mentioned that prices were increasing across many different generic products: "But I must say that we have been able to increase prices on more than just those two products and it's the portfolio of products and their price increases which is driving that gross margin you see."

130. In a quarterly earnings call held on November 3, 2014. Bedrosian again expressed confidence that Lannett would not have to engage in price competition generally for it generics. He said Lannett and its competitors were "less concerned about grabbing market share. We're all interested in making a profit, not how many units we sell." Bedrosian went on to discuss,

inter alia, Par and Impax, saying that "the companies we're looking at here are not irrational players. I don't see them just going out and trying to grab market share." He also noted that Mylan was expected to enter the market, "but Mylan is one of those rational competitors, so we're not really expecting anything crazy from them." He predicted that price increases would continue.

131. Bedrosian stated in a February 4, 2015 earnings call, in response to a question regarding the sustainability of pricing, that,

> So I'm expecting these pricings to really sustain themselves to continue. I see people raising prices further, because the generic prices were so low, when you're 10% of the brand, that's not because the brand overpriced the product by 90%. It's because the generic marketplace has so much competition sometimes, people get desperate just to unload their inventory that they cut the prices.
>
> We don't see that kind of behavior sustainable, and we don't see it going further into the future. I think you're going to find more capital pricing, more – I'll say less competition, in a sense. You won't have price wars. You are still going to have competition, because there's a lot of generic companies in the market.
>
> I just don't see the prices eroding like they did in the past. It's really unfortunate, but what they see some significant pricing, cost increases, I should say, that are driving this.

132. On the same February 4, 2015 earnings call, with respect to digoxin, Bedrosian alerted the other generic suppliers that Lannett stood ready to increase prices again because there was a potential for a market disruption "that certainly could equate to a price increase for us. So I would just say stay tuned. But we're also looking to capture more market share on the Digoxin. This is an important product for us." Bedrosian then immediately offered a warning to other generic manufacturers that they would be prepared to discipline them, "We don't want to sit by and just let our competition take away our market share." As to the recent entrant, Par, whom he had noted was "a rational competitor", he did not fear it would discount to Lannett's pricing:

"Well, discounting to our price, no. We've seen their prices discounted to the brand, of course, but we're not troubled by their pricing in the marketplace. Not at all."

133. A May 2015 presentation by Mr. Bedrosian and Lannett's CFO noted that one of Lannett's strengths was a "track record of selecting products with high profit potential and manageable competition."[45]

b. Impax

134. On November 4, 2013, the then-President of Impax, Carole Ben-Maimon, acknowledged that Impax had increased the price of digoxin after Lannett had increased its price, after noting its medical necessity to patients. In response to a question concerning Impax's "huge price increase on digoxin following Lannett's pricing action," Ben-Maimon stated: "The price increase on dig[oxin] speaks for itself, but clearly, as a medically necessary drug, our focus there is really just to make sure that a high quality product is available to the customer." Ben-Maimon's comments make clear that Impax had no intention of competing for market share for digoxin by offering lower prices; it simply would ensure there was sufficient supply, at its newly increased pricing for its customers.

135. Ben-Maimon demonstrated Impax's continued acceptance of Lannett's invitation to increase prices and noted Impax's commitment to maintaining price increases during a February 2014 earnings call with analysts. Ben-Maimon stated regarding digoxin, "the market has been pretty stable with [Lannett] and us . . . [w]e're pretty comfortable that what we have done is rational and will result in ongoing profitability for that product."

136. The Chief Executive Officer of Impax, Frederick Wilkinson, continued to echo Lannett's message on increasing prices in a third quarter earnings call on November 4, 2014:

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[45] Lannett PowerPoint Presentation, at 7 (May 2015).

> [L]et me address pricing. We really don't talk much about pricing publicly, and whether we're going for competitive reasons but surprising to say we've done what most of the other generic competitors have done, we look at opportunities, we look at how competition shifts, we look at where there may be some market movement that will allow us to take advantages on price increases and we've implemented those and we'll continue to evaluate our line product-by-product probably a week and monthly basis to see if there are some opportunities to participate in that practice.

Wilkinson also acknowledged the federal investigation of pricing in the pharmaceutical industry during that earnings call.

c. West-Ward

137. In 2013, Hikma, parent company to West-Ward, reported that "[s]trong cash flow reflects exceptional profitability of doxycycline"[46]

138. On March 12, 2014, Hikma announced strong revenue growth, driven in part by doxycycline sales, and forecasted continued growth in 2014, which would reflect continued commitment to maintaining its doxycycline pricing. Said Darwazah, Hikma's CEO was "confident about the prospects for 2014," and noted that in 2013, "[o]ur Generics business delivered very strong revenue, driven primarily by doxycycline, and generated significant cash flow."[47]

139. In Hikma's Q2 2014 earnings call, Hikma's CFO stated: "I don't know how many of you have covered U.S. generic companies. But when I look at competitors, I look at the -- most companies that are either U.S. based or have a strong position in the U.S. are doing very well the last few years. So the market forces are changing, I believe, in the market."

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[46] Hikma Pharmaceuticals Preliminary Results (2013).

[47] Press Release, Hikma Pharmaceuticals plc (Mar. 12, 2014). Hikma anticipated potentially reduced doxycycline revenue in the U.S. market in 2014 due to increased competition.

140. In December 2013, Darwazah told Bloomberg Business that West-Ward's huge increases in doxycycline prices were justified because it was "'forced' to raise prices because its competitors raised theirs."[48] This assertion only confirms Bedrosian's statement that his generic drug competitors were no longer interested in competing on price.

d. Sun

141. In 2013, Sun's subsidiary URL "had undertaken price hikes in March" and, as a result of these price increases, Sun estimated "$60-80 million (of $128 million in total revenue for URL estimated ... for FY[20]14) to come from [doxycycline] , with operating margins in the range of 50-55 percent."[49]

142. In 2013 and 2014, Sun reported that its costs were stable. In its quarterly reports during that period, Sun's directors reported that the company's material cost and other expenditures as a percentage of net sales, as well as staff costs, were substantially the same or lower than the same periods in the prior year. For example, Sun reported that net sales increased 40% in fiscal year 2013 compared to 2012 even while "[m]aterial cost, as a percentage of the net sales is 18.5% which is lower as compared to the previous year." Staff costs and other expenditures were also reported to be lower in 2013. Similarly, Sun reported that second quarter 2013-14 costs were also "in-line with Q2 last year."

143. Sun reported in September 2015 and February 2016 investor presentations that one of the "key drivers" of its sales through the period 2012 through 2014 was doxycycline,

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[48] Alan Katz, *Surprise! Generic Drug Prices Spike*, Bloomberg (Dec. 12, 2013), available at https://www.bloomberg.com/news/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise.

[49] Ujjval Jauhari, *Sun Pharma's Prospects Remain Bright*, Business Standard (Sept. 12, 2013), *available at* http://www.business-standard.com/article/markets/sun-pharma-s-prospects-remain-bright-113091200894_1.html

which it described as a "low competition product" in the U.S. - a notable description in light of the large number of competitor products.

e. Mylan

144. In a Q3 2015 earnings call, Mylan's CEO and Mylan's EVP and CFO repeatedly commented on the "positive pricing environment that we've seen, especially over the last couple of years in North America" and that Mylan had "absolutely had opportunities around generic pricing." Mylan executives made similar comments relating to the "positive pricing environment" in earlier earnings calls, such as the Q4 2014 earnings call.

f. Actavis

145. In a Q3 2015 earnings call discussing Teva's acquisition of Actavis, Teva executives commented on "some abnormalities" in pricing generic pharmaceuticals and that the "overall pricing environment has been quite favorable for generics."

g. Par

146. In a May 18, 2015 presentation by Endo International plc concerning its acquisition of Par, Endo noted that "consolidation and maturation of competitors have stabilized the pricing environment" for generic pharmaceuticals in the U.S.

2. Defendants' Collusion Opportunities through Trade Organizations.

147. Defendants have opportunities to communicate and collude through trade organization events, such as conferences, trade shows, and industry dinners. As explained by the Connecticut Attorney General, "the defendants routinely coordinated their schemes through

direct interaction with their competitors at industry trade shows, customer conferences and other events . . . ."[50]

148. According to news reports, the *Policy and Regulatory Report* ("PaRR") obtained information regarding the investigation of generic pharmaceutical companies by the DOJ. According to PaRR, the DOJ is investigating whether trade organizations are a potential vehicle for collusion between salespeople at different generic pharmaceutical companies.[51]

149. For example, the Generic Pharmaceutical Association ("GPhA") is the "leading trade association for generic drug manufacturers and distributors, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry."[52] GPhA was formed in 2000 from the merger of three industry trade associations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

150. Regular Members "are corporations, partnerships or other legal entities whose primary U.S. business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3) biosimilar/biogeneric products; or (4) DESI products."[53]

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[50] Press Release, State of Connecticut Attorney General George Jepsen, *Connecticut Leads 20 State Coalition Filing Federal Antitrust Lawsuit against Heritage Pharmaceuticals, other Generic Drug Companies*, (Dec. 15, 2016), *available at* http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

[51] Eric Palmer, *DOJ Criminal probe takes a look at trade associations*, FiercePharma (July 10, 2015), *available at* http://www.fiercepharma.com/regulatory/doj-criminal-probe-takes-a-look-at-trade-associations.

[52] GPhA Website, The Association, *available at* http://www.gphaonline.org/about/the-gpha-association.

[53] GPha Website, Membership, *available at* http://www.gphaonline.org/about/membership.

151. Several of defendants' high-ranking officers serve on GPhA's Board of Directors, including Mylan's Heather Bresch, Impax's Marcy MacDonald, Par's Tony Pera, and Sun's Jim Kedrowski. Bresch serves as the GPhA's current Chairperson.

152. Defendants Impax and Par have representatives on GPhA's 2016 Board of Directors. Defendant West-Ward is a member of GPhA.

153. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." GPhA states that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections."[54]

154. Representatives from defendants attended meetings held by GPhA. The following table lists some of the GPhA meetings attended by defendants' employees:

Meeting	Meeting Date and Location	Known Attendees
2012 GPhA Annual Meeting	February 22 to 24, 2012 Orlando, Florida	Watson (now Actavis), Mylan, Par
2012 GPhA Fall Technical Conference	October 1 to 3, 2012 Bethesda, Maryland	Actavis , Heritage, Lannett, Impax, Mylan, Par, Sun
2013 GPhA Annual Meeting	February 20 to 22, 2013 Orlando, Florida	Actavis , Impax, Mylan, Par
2013 GPhA Fall Technical Conference	October 28 to 30, 2013 Bethesda, Maryland	Actavis, Heritage, Impax, Lannett, Mylan, Par, Sun
2014 GPhA Annual Meeting	February 19 to 21, 2014 Orlando, Florida	Actavis, Heritage, Impax, Mylan, Par, Sun

[54] GPhA Website, Membership, *available at* http://www.gphaonline.org/about/membership.

Meeting	Meeting Date and Location	Known Attendees
2014 GPhA Fall Technical Conference	October 27 to 29, 2014 Bethesda, Maryland	Actavis, Heritage, Impax, Lannett, Mylan, Par, Sun, West-Ward
2015 GPhA CMC Workshop	June 9 to 10, 2015 Bethesda, Maryland	Actavis, Heritage, Impax, Lannett, Mylan, Par, Sun, West-Ward

155. Generic pharmaceutical manufacturers attend such meetings and industry trade shows throughout the year. Industry trade shows are hosted by GPhA, National Association of Chain Drug Stores ("NACDS"), Healthcare Distribution Management Association ("HDMA") (now the Healthcare Distribution Alliance), Efficient Collaborative Retail Marketing ("ECRM"), and others.[55] At these meetings and trade shows, generic pharmaceutical manufacturers have opportunities to discuss and share competitively sensitive information, such as pricing, upcoming bids, and customer contracts.[56] As discussed above, the AG Complaint demonstrates that generic pharmaceutical manufacturers took advantage of these opportunities.

156. High-level executives of generic pharmaceutical manufacturers meet periodically at industry dinners. For example, in January 2014, when certain generic pharmaceutical prices were increasing exponentially, at least thirteen high-ranking executives of various generic pharmaceutical manufacturers met at a steakhouse in Bridgewater, New Jersey.[57]

157. Female sales representatives for generic pharmaceutical manufacturers regularly hold meetings and dinners for "Girls Night Out" ("GNO") and Women in the Industry events,

[55] *See* AG Complaint at ¶ 50.
[56] *Id.* at ¶ 51.
[57] *Id.* at ¶ 55.

where competitively sensitive information is discussed.[58] For example, GNOs were held at the ECRM conference in February 2015, in Baltimore in May 2015 (involving Heritage and others), and at the NACDS conference in August 2015 (involving Heritage and others).[59] Participants in the Women in Industry events were typically organized by a sales representative from Heritage.[60]

3. Defendants' Concerted Efforts Yield Supra-Competitive Profits

158. The meeting of the minds among the competing sellers of generic digoxin and generic doxycycline hyclate assured them handsome profits. Bedrosian noted in the February 4, 2015 earnings call that Lannett "recorded the highest net sales and net income in our company's history." Gross profits in the first six months of the 2015 fiscal year were $158.8 million or 76% of net sales, compared with $42.3 million or 37% of net sales during the previous fiscal year. Generic digoxin accounted for 23% of the company's revenues, and Lannett has acknowledged that it is highly dependent on price increases for revenue growth.

159. Similarly, according to its 2015 SEC Form 10-K filed on February 26, 2015, Impax's 2014 revenues were $596 million, compared to $511 million in 2013—a 17% increase. One of the primary factors in this growth was "higher sales of our digoxin."

160. Likewise, Hikma, West-Ward's parent, said in a 2014 press release that its generic drug revenues increased by 158%, "reflecting very strong doxycycline sales."[61] And Sun reported in 2013 that price increases earlier in the year yielded "$60-80 million (of $128 million

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[58] *Id.* at ¶ 57.
[59] *Id.* at ¶ 60.
[60] *Id.* at ¶ 58.
[61] Press Release, Hikma Pharmaceuticals (Mar. 12, 2014), *available at* http://www.hikma.com/~/media/Files/H/Hikma/Attachments/pdf/prel-res-pres-12032014a.pdf.

in total revenue…) to come from [doxycycline], with operating margins in the range of 50-55%."[62]

161. In an August 28, 2015 FY15 Results Presentation, Mayne reported that U.S. "revenue uplift [was] driven by," among other products, doxycycline. And in a September 9, 2015 Company Presentation, Mayne reported that it would be able to optimize doxycycline sales through "[f]urther product pricing improvements."

162. Defendants' agreement to inflate the prices of generic drugs led to increased revenue and higher profits – which was a motive for the conspiracy. In addition, the burgeoning profits of the illegal scheme drove company share prices higher, which provided further motive to conspire. For example, Lannett's stock price in October 2012 was under $5. But by April 2015, Lannett's share price had skyrocketed to more than $70, fueled by the inflated profits from generic drugs. Bedrosian, the Lannett CEO, owned more than 600,000 shares of stock during this time frame, the value of which increased by tens of millions of dollars. Other defendants' stock prices also exploded with the profits of their price-fixing scheme. For example, the share prices of Mylan, Hikma and Sun approximately tripled between October 2012 and mid-2015.

4. Industry Commentary

163. Industry analysts have also questioned manufacturers' claims that price increases are due to supply disruptions. Indeed, Richard Evans at Sector & Sovereign Research recently wrote: "[a] plausible explanation [for price increases of generic drugs, including generic digoxin] is that generic manufacturers, having fallen to near historic low levels of financial performance

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[62] Ujival Jauhari, *Sun Pharma's Prospects Remain Bright*, Business Standard (Sept. 12, 2013), *available at* http://www.business-standard.com/article/markets/sun-pharma-s-prospects-remain-bright-113091200894_1.html.

are cooperating to raise the prices of products whose characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation."[63]

164. Mark Rosman, former assistant chief of the National Criminal Enforcement Section of DOJ's Antitrust Division, noted in an article on the "unusual" nature of the criminal subpoenas: "A DOJ investigation into the alleged exchange of pricing information in the pharmaceutical industry likely indicates that the agency anticipates uncovering criminal antitrust conduct in the form of price-fixing or customer allocation."[64]

165. Another commentator noted on a legal website:

> The Justice Department's subpoenas focus on sharing and exchanging of pricing information and other issues among generic drug companies. The initial subpoenas, including two senior executives, suggest that the Justice Department has specific information relating to their participation in potentially criminal conduct. It is rare for the Justice Department to open a criminal investigation with specific subpoenas for individuals, along with company-focused subpoenas.
>
> Given the breadth of such a potential cartel investigation, the Justice Department's inquiry of the generic pharmaceutical industry could be significant. The prices for a large number of generic drug prices have increased significantly over the last year. There does not appear to be any rational explanation for such increases involving a diverse set of products.
>
> The scope of these price increases and the timing of them certainly raise serious concerns about collusive activity among competitors.[65]

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[63] Ed Silverman, *Generic Drug Prices Keep Rising, but is a Slowdown Coming?*, Wall Street Journal (Apr. 22, 2015), *available at* http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-a-slowdown-coming/.

[64] Mark Rosman, *DOJ's Investigation into Generic Pharma Pricing is Unusual*, Law360 (Nov. 12, 2014), *available at* https://www.wsgr.com/publications/PDFSearch/rosman-1114.pdf.

[65] Michael Volkov, *Criminal Global Cartel Focus on Generic Pharmaceuticals*, JDSupra (Nov. 26, 2014), *available at* http://www.jdsupra.com/legalnews/criminal-global-cartel-focus-on-generic-92387/.

5. Defendants' Claims that Rising Costs Justified the Price Increases Were Pretextual

166. Defendants often cited to increased costs to justify their collusive price increases.

167. That these justifications were pretextual is demonstrated by the fact that throughout the period, defendants were making record or unprecedented profits from their generic products.

168. Lannett's sales reported in February 2014 were the best in the company's history, and Lannett was able to increase its profit guidance on the strength of the price increases.

169. In 2013, Hikma reported that "[s]ales of doxycycline generated exceptionally strong cash flows" and Hikma used some of that cash flow to help "paydown of debt of $117 million."[66]

170. In 2013 and 2014, Sun reported that its costs were stable. In its quarterly reports during that period, Sun's directors reported that the company's material cost and other expenditures as a percentage of net sales, as well as staff costs, were substantially the same or lower than the same periods in the prior year. For example, Sun reported that net sales increased 40% in fiscal year 2013 compared to 2012 even while "[m]aterial cost, as a percentage of the net sales is 18.5% which is lower as compared to the previous year."[67] Staff costs and other expenditures were also reported to be lower in 2013.[68] Similarly, Sun reported that second quarter 2013-14 costs were also "in-line with Q2 last year."[69]

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[66] Hikma Pharmaceuticals Preliminary Results (2013).
[67] Sun Pharma Q4 2012 Earnings Call Transcript (May 28, 2013).
[68] *Id.*
[69] Sun Pharma Q2 2013 Earnings Call Transcript (Nov. 14, 2013).

F. History of Government Investigations

171. As noted above, defendants' conduct in generic pharmaceutical pricing is the subject of federal government investigations by the U.S. Senate and DOJ, as well as state government investigations.

172. In July 2014, Lannett reported that it and "at least one of its competitors" received a subpoena and interrogatories from the Connecticut Attorney General's Office concerning its investigation into the pricing of digoxin. According to Lannett's 2014 Annual Report, the Connecticut Attorney General was "investigating whether anyone engaged in any activities that resulted in (a) fixing, maintaining or controlling prices of digoxin or (b) allocating and dividing customers or territories relating to the sale of digoxin in violation of Connecticut antitrust law." In fact, two of Lannett's competitors, Impax and Par, were subpoenaed by the Connecticut Attorney General in relation to the pricing of digoxin. Mylan N.V., parent company to Mylan Pharmaceuticals, Inc., reported on February 16, 2016 in its 10-K that, "[o]n December 21, 2015, the Company received a subpoena and interrogatories from the Connecticut Office of the Attorney General seeking information relating to the marketing, pricing and sale of certain of the Company's generic products (including Doxycycline) and communications with competitors about such products."

173. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Representative Elijah E. Cummings sent letters to fourteen pharmaceutical manufacturers, including defendants Lannett, Par, Actavis, Global Pharmaceuticals (a subsidiary of Impax), Heritage, Mylan, Sun Pharmaceuticals, and West-Ward, seeking information relating to the escalating prices of generic pharmaceuticals (the "October Letters").

174. The October Letter to Lannett, for example, states,

> We are writing to your company to request information about the escalating prices it has been charging for two drugs: Digoxin and Doxycycline Hyclate, which are used to treat certain types of irregular heartbeats and heart failure, and to treat a variety of infections, respectively. According to data provided by the Healthcare Supply Chain Association (HSCA), the average price charged for this drug has increased by as much as 8281 percent from October 2013 to April 2014. Over that time period, the average market price went up by as much as $1,829. Additionally, according to National Average Drug Acquisition Cost Data provided by HSCA, the average price charged for Digoxin has increased by as much as 884 percent from October 2012 to June 2014.[70]

175. In Lannett's October Letter, Senator Sanders and Congressman Cummings seek the following information and documents from January 1, 2012 to the present:

(1) Total gross revenues from the company's sales of these drugs;

(2) The dates, quantities, purchasers, and prices paid for all sales of these drugs;

(3) Total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;

(4) Sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;

(5) A description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the prices of these drugs;

(6) Any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;

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[70] *See* Letter from Bernie Sanders, U.S. Senator, and Elijah Cummings, U.S. Representative, to Arthur P. Bedrosian, Chief Executive Officer, Lannett Co., Inc. (Oct. 2, 2014), *available at* http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file.

(7) Prices of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest prices; and

(8) The identity of company official(s) responsible for setting the prices of these drugs over the above time period.

Lannett's October Letter provided that the requested information and documents be turned in to congressional offices by October 23, 2014.

176. The U.S. Senate HELP Committee held the Senate Hearing on November 20, 2014 (*Why Are Some Generic Drugs Skyrocketing in Price?*). Lannett's CEO, Bedrosian, was invited to testify but did not attend the hearing.[71]

177. During the Senate Hearing on generic pharmaceutical prices, pharmacist Rob Frankil testified on November 20, 2014 that, "it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs."[72] According to Frankil, digoxin and doxycycline were two of the generic pharmaceuticals with price spikes. With respect to digoxin, Frankil stated that,

> A recent example from my own experience is the price of Digoxin- a drug used to treat heart failure. The price of this medication jumped from about $15 for 90 days' supply, to about $120 for 90 days' supply. That's an increase of 800%. One of my patients had to pay for this drug when he was in the Medicare Part D coverage gap in 2014. Last year, when in the coverage gap he paid the old price. This year he paid the new price. Needless to say, the patient was astounded, and thought I was overcharging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price

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[71] U.S. Senator Bernie Sanders Press Release, *Drugmakers Mum on Huge Price* Hikes (Nov. 20, 2014), *available at* http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes.

[72] Testimony of Rob Frankil, U.S. Senate Hearing, *Why Are Some Generic Drugs Skyrocketing in Price?* (Nov. 20, 2014), *available at* http://www.help.senate.gov/imo/media/doc/Frankil.pdf.

> spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the federal government).[73]

178. Subsequent congressional hearings concerning the dramatic rise of generic pharmaceutical prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging's December 9, 2015 hearing, Erin D. Fox, the Director of the Drug Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating that "[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."

179. The DOJ opened a criminal grand jury investigation into defendants' conduct on or about November 3, 2014. Grand jury subpoenas have been issued to, among other generic pharmaceutical companies, defendants Lannett, Lannett's Vice-President of Sales and Marketing, Impax, an unidentified sales representative of Impax, Actavis, Par, Sun Pharmaceuticals, Mylan, and Mayne. Upon information and belief, Lannett's Vice-President of Sales and Marketing is Kevin Smith.

180. The fact that grand jury subpoenas were served on defendants is indicative that they have potentially violated antitrust law. According to the DOJ's *Antitrust Division Manual*, "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a

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[73] *Id.*

criminal prosecution."[74] If a grand jury request memorandum is approved by the DOJ field office chief, "a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division]."[75] "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation."[76] Then, "[t]he investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."[77]

181. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter to the Office of the Inspector General ("OIG") of the Department of Health and Human Services asking that the OIG "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs."[78] The OIG responded to the request on April 13, 2015 and stated that it planned to review quarterly average manufacturer prices ["AMPs"] for the top 200 generic drugs

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[74] *See* Antitrust Division Manual, Chapter III, Section F.1 at III-82 (Apr. 2015), *available at* https://www.justice.gov/atr/division-manual.

[75] *Id.*

[76] *Id.* at III-83.

[77] *Id.*

[78] Letter from Bernie Sanders, U.S. Senator, and Elijah Cummings, U.S. Representative, to Daniel R. Levinson, Inspector General, Department of Health and Human Services (Feb. 24, 2015), *available at* http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

from 2005 through 2014, and would "determine the extent to which the quarterly AMPs exceeded the specified inflation factor."[79]

182. Lannett's 10-Q report dated February 6, 2015, discloses that on November 3, 2014, "the Senior Vice-President of Sales and Marketing was served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act," and that on December 5, 2014, "[t]he Company was served with a grand jury subpoena related to the federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoena requests corporate documents from the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale or pricing of certain products."

183. Lannett similarly disclosed in its annual report for fiscal year ending June 30, 2015, that it was served with a grand jury subpoena for documents relating to communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale or pricing of certain products, generally for the period of 2005 through the dates of the subpoenas.

184. Lannett also reported that "Levothyroxine Sodium and Digoxin collectively accounted for 50% of our net sales in fiscal year 2015," and "[n]et sales of [digoxin] totaled $49.0 million in fiscal year 2015."

185. Par, Impax, Actavis, Mylan, and Sun have also disclosed in SEC filings that they have been served with subpoenas.

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[79] Letter from Daniel R. Levinson, Inspector General, Department of Health and Human Services, to Bernie Sanders, U.S. Senator (Apr. 13, 2005), *available at* http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

186. Par's 10-K dated March 12, 2015 disclosed that it had received a subpoena from the Antitrust Division of the DOJ requesting documents related to communications with competitors regarding its authorized generic version of Covis's Lanoxin (digoxin) oral tablets.

187. Par's parent company, Endo, stated in a 10-Q for the third quarter of 2015 that it also had received a subpoena for information focused primarily on pricing for Par's authorized generic version of Lanoxin (digoxin) oral tablets and generic doxycycline products.

188. Impax's 2015 annual report dated February 22, 2016 disclosed that one of its sales representatives received a grand jury subpoena from the DOJ and that the company had also received a grand jury subpoena from DOJ for documents concerning sales, marketing, and pricing of certain generic prescription medications concerning digoxin tablets and other pharmaceuticals.

189. Allergan's February 26, 2016 10-K for fiscal year ending December 31, 2015 disclosed that its Actavis division received a subpoena from DOJ for information relating to the marketing and pricing of multiple generic products and communications with competitors about such products.

190. Mylan N.V. reported in its 10-K for fiscal year ending December 31, 2015 that a subsidiary received a subpoena from DOJ for information relating to generic doxycycline products and communications with competitors about such products.

191. On May 28, 2016, Sun disclosed that it had received a DOJ subpoena related to Sun's pricing and marketing of generic pharmaceuticals in the U.S.[80]

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[80] *See* Zeba Siddiqui, *India's Sun Pharma Gets Subpoena over Generic Drug Pricing*, Reuters (May 28, 2016), *available at* http://www.reuters.com/article/sun-pharm-usa-idUSL4N18P00X.

192. Mayne reported in two separate releases, and annual report for 2016 and a press release dated November 4, 2016, that it was subpoenaed by both DOJ and the Connecticut Attorney General related to pricing of generic products including doxycycline.

193. The first indictments to result from the DOJ's investigation of the generic drug industry were filed in the Eastern District of Pennsylvania in December 2016 against former executives of Heritage, Glazer and Malek. And, those individuals have since pleaded guilty.

194. As a result of the Attorney Generals' investigation of the generic pharmaceutical industry, the AG Complaint was filed in December 2016. This complaint provides additional details on Heritage's anticompetitive conduct in certain generic pharmaceutical markets. According to the AG Complaint, "[i]n July 2014, the State of Connecticut initiated a non-public investigation into suspicious price increases for certain generic pharmaceuticals. The information developed through that investigation, which is still ongoing, uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the U.S."[81]

195. With respect to Doxy DR, the AG Complaint alleges that Heritage employees communicated and coordinated with Mylan and Mayne regarding Doxy DR pricing, market share, and bids.[82] Heritage entered the market for Doxy DR in July 2013, when the only other competitor was Mylan. Prior to Heritage's entering the market, Heritage executives contacted a Mylan employee in May 2013 regarding Doxy DR and entered an agreement to allocate market share and refrain from competing. Mylan and Heritage coordinated on bidding for Doxy DR

[81] *See* AG Complaint at ¶ 1.
[82] *Id.* at ¶¶ 70-100.

throughout 2014. Heritage executives made clear that the purpose of the agreement was to maintain high prices.

196. Mayne Pharma entered the market for Doxy DR in February 2014 and approached Heritage prior to entering the market regarding obtaining market share. Heritage and Mayne ultimately began coordinating on bidding. For example, in January 2015, Econdisc Contracting Solutions, a large group purchasing organization, sought bids for Doxy DR, and Heritage made sure to bid a higher price than Mayne in accordance with the agreement not to compete. In September 2015, Heritage also refused to provide a Doxy DR bid to a large pharmacy chain, because the incumbent supplier was Mayne.

197. The AG Complaint alleges various specific instances of anticompetitive activity including:

- An instance where Mylan agreed to "walk away" from large orders and allow Heritage to obtain the business and increase its market share.

- An instance in November 2013 where Heritage and Mylan discussed the fact that the purpose of their agreement was to maintain high prices and ensured that both companies were committed to that goal.

- An instance in February 2014 where Mayne approached Heritage to discuss allocating the market for Doxy DR.

- Instances in early to mid-2014 where Heritage and Mayne engaged in bid-rigging related to Doxy DR.

- An instance in August 2014 where Heritage communicated with Mylan concerning their agreement to fix prices.

- An instance in November 2014 where Heritage and Mayne engaged in bid-rigging related to Doxy DR.

- An instance in December 2014 where Heritage and Mayne employees met at a trade association conference to discuss their illegal agreement.

- An instance in December 2014 where Mayne followed through on its agreement with Heritage to rig bids on Doxy DR.

- An instance in December 2015 where Heritage and Mayne engaged in bid-rigging related to Doxy DR.

198. The above instances are part of what the state attorneys general described as a "wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time" as a result of their ongoing investigation. DOJ and state government investigations of defendants' alleged price-fixing conduct in the generic pharmaceutical industry continue.

199. Based on the information developed in the state AG's investigation, the AG Complaint alleges that Heritage was "[t]he principal architect and ringleader of the conspiracies"

to fix the prices, allocate markets, and rig bids for, *inter alia*, doxycycline hyclate extended release.[83]

200. One of the targets of the DOJ investigation has reportedly applied for leniency. This is significant because the applicant must admit to participation in a criminal antitrust violation. As the DOJ notes on its web site:

> 5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?
>
> Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.[84]

201. The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession

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[83] *See* AG Complaint at ¶ 10.

[84] Frequently Asked Questions Regarding the Antitrust Division's Leniency Program, Dept. of Justice (last visited Jan. 24, 2017), *available at* http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program

of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials."[85]

VII. THE GENERIC PHARMACEUTICAL MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

202. Defendants' anticompetitive conduct constitutes a conspiracy to fix prices that is a *per se* violation of Section 1 of the Sherman Antitrust Act, plaintiffs do not need to define a relevant market for purposes of proving liability. However, there are features of the markets relevant to this case – digoxin tablets, doxycycline hyclate tablets and doxycycline hyclate delayed release products – that show both (i) that these markets are susceptible to collusion and (ii) that the price increases and market allocations were in fact the result of collusion and not the result of conscious parallelism.

203. **High Degree of Industry Concentration.** Each of the markets had a small number of competitors controlling a significant market share for generic digoxin and generic doxycycline. In particular, for generic digoxin tablets the combined market share of the defendants was about 80% in 2012, and grew to about 91% in 2013 and 97% in 2014. For doxycycline hyclate tablets, the combined market share of the defendants reached similar levels. For generic doxycycline delayed release products, the defendants' market share was nearly 100%.

204. **Sufficient Numbers to Drive Competition.** While each of the markets had a small enough number of competitors to foster collusion, the number of makers was large enough that – given decades of experience with competitive generic pricing, and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at

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[85] *Id.*